

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated September 6, 2007 are respectfully requested. A separate petition for a one-month extension of time accompanies this amendment.

I. Amendments

Claim 28 is amended for proper grammar. No new matter is added by way of this amendment.

II. Double-Patenting Rejection

Claims 1-4 and 28-29 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of pending application serial no. 10/754,351. The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36 C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground.

Enclosed herewith is an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any patent issuing on the instant application that extends beyond the expiration of any patent that issues from U.S. Patent Application No. 10/754,351.

Applicants submit that Terminal Disclaimer overcomes the rejection for obviousness-type double patenting and withdrawal of the rejection is respectfully requested.

III. Rejections under 35 U.S.C. § 103

Claims 1-4 were rejected under 35 U.S.C. §103 as being obvious over WO 99/62496 to Ayer *et al.* (hereinafter “the ‘496 application”) in view of Jao *et al.* (U.S. Patent No. 5,252,338) and further in view of Eckenhoff *et al.* (U.S. Patent No. 4,717,566) and Theeuwes (U.S. Patent No. 4,111,202).

Claims 28-29 were rejected under 35 U.S.C. §103 as being obvious over the '496 application in view of *Jao et al.* and further in view of *Eckenhoff et al.* and *Theeuwes* and the Physician's Desk Reference.

These rejections are respectfully traversed for the following reasons.

A. The Present Claims

The present claims describe a dosage form having an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.

B. The Applied Art

WO 99/62496 (the '496 application) describes an oral dosage form that releases drug within a gastrointestinal tract at an ascending release rate over an extended period of time. In the tri-layer oral osmotic dosage form, a tablet core is surrounded by a semipermeable membrane that has an exit for releasing the drug formulation through the membrane. The tablet core has a first drug-containing layer, a second drug-containing layer and a third push layer.

Jao et al. describe a dosage form having a compartment having a drug composition and an osmotic composition. The wall surrounding the compartment comprises chemical means for slowing the rate of fluid imbibitions through the wall into the compartment (Col. 4, lines 59-61). The drug composition comprises the drug and polymeric means for delaying the delivery of drug (Col. 4, lines 4-6). Further, the compartment may include a layer positioned between the wall and the compositions in the inner compartment (21 in Fig. 3). This layer comprises a polymer to slow or delay the rate of fluid imbibition into the compartment (Col. 5, lines 2-5).

Eckenhoff et al. describe a dosage form designed for retention in the ruminant of an animal. The dosage form includes a thermoresponsive drug layer, an expandable layer, and a dense layer. The dense layer (20 in Figs. 2-8) is prepared from materials having a density of from about 0.8-82, such as iron, iron shot, stainless steel, copper oxide (Col. 12, lines 44-65). The dense member can be "machined or cast as a single, solid piece made of stainless steel....having a curved shape that corresponds to the internal shape of" the dosage form (Col. 12, lines 57-61).

Theeuwes describes a dosage form having two compartments separated by a film or membrane (Col. 5, lines 27-35).

Physician's Desk Reference lists cyclobenzaprine HCl.

C. Analysis

C1. Rejection of Claims 1-4 and 28-29

The amended claims describe a dosage form having a delay layer and a drug layer, where the interface boundary between the delay layer and the drug layer is convex in shape relative to the exit orifice in the dosage form. This combination of features is not shown nor suggested by the combined teachings of the '496 application, Jao *et al.*, Eckenhoff *et al.*, and Theeuwes. Specifically, none of the references show or suggest a convex interface between a delay layer and a drug layer.

The '496 application describes a dosage form with one or two drug layers and a push layer, but no delay layer. Jao *et al.* describe a wall surrounding the inner compartment that comprises chemical means for slowing the rate of fluid imbibitions through the wall into the compartment. As noted by the Examiner, Jao *et al.* fail to teach the convex geometry as in the present claims (page 6, Office action mailed September 6, 2007). Thus, the combined teachings of the '496 application and of Jao *et al.* fail to show or suggest a convex interface boundary layer between a delay layer and a drug layer in a dosage form.

The cited documents of Eckenhoff *et al.* and Theeuwes also do not show or suggest a convex interface between a delay layer and a drug layer. Presumably these documents were cited based on the illustrations in the drawings of dosage forms, wherein a convex "dense member" (Eckenhoff *et al.*) or a convex film or membrane (Theeuwes) are shown. However, the dense member of Eckenhoff *et al.* is not a delay layer, and is not positioned between a drug layer and the exit orifice. Thus, a combination of the '496 application, Jao *et al.* and Eckenhoff *et al.* does not arrive at the presently claimed dosage form. In Theeuwes, the film or membrane that separates two compartments in a dosage form is also not a delay layer, nor would this element guide a skilled artisan to imagine a convex boundary between a delay layer and a drug layer, as presently claimed.

Accordingly, the present claims are not obvious over the teachings of the cited references and withdrawal of the rejection is respectfully requested.

C2. Rejection of claims 28-29

As noted above, the combination of the '496 application, Jao et al., Eckenhoff et al., and Theeuwes fails to show or suggest a convex interface between a delay layer and a drug layer. The Physician's Desk Reference is cited merely for a teaching of cyclobenzaprine. The Reference makes no mention of dosage forms as presently claimed or specifically of a convex interface between a delay layer and a drug layer.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

IV. Conclusion

In view of the foregoing, the claims pending in the application patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 564-2024.

Respectfully submitted,

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